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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/747,385	12/22/00	ATTARIAN G	2307E-099810

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EXAMINER	
DAVIS K	
ART UNIT	**PAPER NUMBER**
1636	5

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/747,385	Applicant(s) ATTARIAN ET AL.	
	Examiner Katharine F. Davis	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10 & 11* is/are allowed.

6)☒ Claim(s) *1-9 and 12-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is in response to the application filed on December 22, 2000 and to the Preliminary Amendment filed April 27, 2001. Claims 1-63 are pending in the instant application.

Claim Objections

Claims 1, 4, 33, 35, 40 and 58-60 are objected to because of the following informalities:

Claim 1 recites the abbreviation *F. nucleatum* in line 1. An abbreviation should be defined upon first appearance in the claims. Appropriate correction is required.

Claims 4, 33 and 40 contain nucleotide and/or amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the claims fail to comply with the requirements of 37 CFR 1.821 through 1.825 because the sequences recited in the claims are not identified by a SEQ ID NO. This objection may be overcome by amending the claim(s) to recite, for example "...nucleotide position 3936 to 4481 of SEQ ID NO..."

Claim 35 recites the term "have". This is grammatically incorrect.

Applicant is advised that should claim 58 be found allowable, claim 60 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 36 and 48 are drawn to specific plasmids (vectors) (pFN2, pFN3 and pHS17). Because it is not clear that the identical plasmids are freely available or can be reproducibly isolated from nature a biological deposit of each plasmid for patenting purposes is required.

The requirements for description and enablement may be met by depositing the cell line in a recognized depository. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant or a statement by an attorney of record over his or her signature and registration number, stating that the specific material has been deposited under the Budapest Treaty and that the material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the requirements of 37 CFR 1.801-1.809 (see Federal Register, Vol. 54, No. 161, issued August 2 1989), Applicant may provide assurance of compliance by an affidavit or declaration or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
(d) the deposit will be replaced if it should ever become inviable.

Applicant must furthermore submit a viability statement consisting of:

(1) the name and address of the depository;
(2) the name and address of the depositor;
(3) the date of deposit;
(4) the identity of the deposit and the accession number given by the depository;
(5) the date of the viability test;
(6) the procedures used to obtain a sample if the test is not done by the depository; and
(7) a statement that the deposit is capable of reproduction.

A viability statement is not required for deposits made under the Budapest Treaty.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12-32, 37-47 and 49-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, 12, 21, 27 and 41 recite the phrase "... for *F. nucleatum*..." It is unclear what is meant by this phrase therefore rendering the claims indefinite. For example, was the

sequence(s) isolated from *F. nucleatum* or is the sequence(s) any sequence functional in *F. nucleatum*?

Claims 1, 5, 6, 9, 12-15, 21-23, 27-29, 37 and 41-43 recite either the term "having" or "has". The terms "having" or "has" are not legally defined as opened or closed language thereby rendering the claims unclear. It is required that the claim language be open (comprising) or closed (consisting of).

Claims 5, 21, 27 and 41 recite the phrase "...selectively binding to polyclonal antibodies..." in step (b). The claims are drawn to nucleic acid sequences however a polypeptide (protein) binds an antibody not a nucleic acid sequence.

Claim 12 recites "having" in line 2 and "selectively binding" in step (b). This is unclear language.

Claim 26 recites the phrase "...wherein the nucleic acid encoding a RepA protein..." There is insufficient antecedent basis for this phrase in the claim.

Claims 58-63 recite incomplete methods. There is no positive process step which clearly relates back to the method(s) recited in the preamble.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 15-17, 21-23, 27-29, 33 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Kinder Haake *et al.* (Journal of Dental Research 78(abstracts):420, abstract No. 2498 1999). This rejection is made assuming that the date of publication of the Kinder Haake *et al.* abstract is prior to December 27, 1999. Kinder Haake *et al.* disclose a DNA analysis of a plasmid (pFN1) isolated from *Fusobacterium nucleatum*. Plasmid pFN1 contains a nucleic acid (SEQ ID NO:2) that encodes for a RepA protein (SEQ ID NO:1). The RepA protein disclosed by Kinder Haake *et al.* would intrinsically have the following properties: a molecular weight of 44.8 kilodaltons and the ability to selectively bind polyclonal antibodies generated against SEQ ID NO:1. Kinder Haake *et al.* disclose that the pNF1 plasmid can be used in gene transfer systems for replication of genes isolated from *Fusobacterium nucleatum*. Plasmid pFN1 contains six 22 base-pair repeats (iterons, SEQ ID NO:3). The iterons are contained in the origin of replication (SEQ ID NO:4). Claims 5-9, 15-17, 21-23, 27-29, 33 and 34 read on the plasmid (and protein encoded by the plasmid) of Kinder Haake *et al.*

Claims 5-9, 15-34, 37-45 and 47-63 are rejected under 35 U.S.C. 102(a) as being anticipated by Kinder Haake *et al.* (Abstracts of the General Meeting of the American Society of Microbiology 99:331, Abstract No. H-9, May 1999). Kinder Haake *et al.* disclose the pNF1 plasmid isolated from *Fusobacterium nucleatum.* Plasmid pFN1 contains a nucleic acid (SEQ ID NO:2) that encodes for a RepA protein (SEQ ID NO:1). The RepA protein disclosed by Kinder Haake *et al.* would intrinsically have the following properties: a molecular weight of 44.8 kilodaltons and the ability to selectively bind polyclonal antibodies generated against SEQ ID NO:1. Kinder Haake *et al.* disclose that the pNF1 plasmid can be used in gene transfer systems for replication of genes isolated from *Fusobacterium nucleatum*. Plasmid pFN1 contains six 22 base-pair repeats (iterons, SEQ ID NO:3). The iterons are contained in the origin of replication (SEQ ID NO:4). In this abstract Kinder Haake *et al.* further disclose pFN1 having an antibiotic resistance marker gene (erythromycin). Kinder Haake *et al.* also further disclose an intergeneric shuttle vector (pHS17). The shuttle vector is made by recombinantly inserting sequences from *F. nucleatum* (for example, RepA and/or the origin of replication) into a plasmid isolated from *E. coli*. Kinder Haake *et al.* disclose host cells (*F. nucleatum* and *E. coli*) and a method of transforming said host cells for the purpose of studying gene expression in *F. nucleatum*. Claims 5-9, 15-34, 37-45 and 47-63 read on the plasmid, protein encoded by the plasmid, shuttle vectors, host cells and methods of Kinder Haake *et al.*

Claims 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by McKay *et al.* (Plasmid 33:15-25 1995). McKay *et al.* disclose a plasmid(s) derived from *Fusobacterium nucleatum* that can be used for replication of genes (in *Fusobacterium nucleatum*, see Table 1, page 20). The plasmid(s) of McKay *et al.* comprises a nucleic acid encoding a protein with 97.2% sequence identity to SEQ ID NO:1 (RepA). The RepA protein disclosed by McKay *et al.* would intrinsically have the following properties: a molecular weight of 44.8 kilodaltons and the ability to selectively bind polyclonal anitbodies generated against SEQ ID NO:1. Claims 5, 7 and 8 read on the plasmid(s) of McKay *et al.*

Conclusion

Claims 1-9 and 12-63 are rejected. Claims 10 and 11 are allowable. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is

(703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis
September 8, 2001

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER